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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,157

01/27/2006

Shigeo Shibatani

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EXAMINER

BAGGOT, BRENDAN O

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

08/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,157	Applicant(s) SHIBATANI ET AL.	
	Examiner Brendan O. Baggot	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-15 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Final Rejection

1. The text of those sections of title 35 U.S.C. not included in this action can be found in a prior Office action.
2. The rejection of Claim 1 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention is withdrawn in light of Applicant's arguments filed 4/24/07.
3. The rejection of Claims 9-13, 15 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in light of Applicant's arguments filed 4/24/07.
4. The Office acknowledges the receipt of Applicant's Response, Exhibits and Claim amendments filed 4/24/07. Claim 22 is newly added.
5. The Office acknowledges that claims 20-21 are withdrawn.
6. Claims 1-5 and 8-15 are examined.

Claim Rejections - 35 USC § 112, 1st, paragraph, written description

7. Claims 1-5 and 8-15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth in the Official action mailed 1/24/07 as applied to Claims 1-19. Applicant's arguments filed 4/24/07 have been fully considered but are deemed not persuasive.

Applicant urges that the claims have been amended to recite the *Chlorella* HAS gene, which the prior Office action said was adequately described (Applicant's Response, filed 4/24/07, page 9).

This is not persuasive because the claims are directed to a HAS with "one or more amino acid deletions, substitutions, additions or insertions. . ." (claim 1, lines 5-6). Applicant has not disclosed such HASs. Therefore, the claims are not adequately described.

Claim Rejections - 35 U.S.C. §112, first paragraph, enablement

8. Claims 1-5 and 8-15 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *Chlorella* HAS gene, does not reasonably provide enablement for any HAS from any species or any sequence variants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the claimed invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth in the Official action mailed 1/24/07 as applied to Claims 1-19. Applicant's arguments filed 4/24/07 have been fully considered but are deemed not persuasive.

Applicant urges that the claims have been amended to recite the Chlorella HAS gene which the prior Office action said was adequately enabled (Response, filed 4/24/07, page 9).

This is not persuasive because the claims are directed to a HAS with "one or more amino acid deletions, substitutions, additions or insertions. . ." (Applicant's Response, filed 4/24/07, page 9, claim 1). Applicant has not disclosed such HASs. Therefore, the claims are not enabled.

Claim Rejections - 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

9. Claims 1-5 and 8-15 remain and 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smeekens et al (6147280-US, Issued 14 November 2000) in view of DeAngelis, et al., (1997) Science 278:1800-1803 and further in light of Akasaka 4801539-US, issued 31 January 1989) and Mattes, et al., (5985668-US, Issued 16 November 1999).

This rejection is maintained for reasons of record set forth in the Official action mailed 1/24/07 as applied to Claims 1-5 and 8-15. Applicant's arguments filed 4/24/07 have been fully considered but are deemed not persuasive.

Applicant urges that "... none of the references alone teach the composition as claimed." (Response, page 10, 1st parag.).

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This is not persuasive because the test for obviousness does not require all the teachings be in a single reference.

Applicant urges that there "is a lack of motivation to combine the references because Smeekens is directed to a method of producing oligosaccharides. . . ." (Applicant's Response, filed 4/24/07, pages 9-11) and therefore, Smeekens teaches away from a polysaccharide with a high degree of polymerization. (Response, page 10, 1st parag.).

This is not persuasive because Smeekens teaches more than just oligosaccharides, teaches or suggests more than just fructans and because it is well known to the ordinarily skilled artisan that plants already contain one of the largest polymers built from small sugars known to man: starch.

Smeekens also teaches the *SacB* gene from *Bacillus subtilis*, which is well known to the ordinarily skilled artisan to produce large polymers from carbohydrate building blocks. (claim 8).

Smeekens also teaches that it is known that incorporating the *SacB* gene into plants will alter the high molecular weight fructan pattern of plants. (Smeekens, column 4, lines 1-50, particularly lines 7-10).

Finally, as admitted by Applicant, "hyaluronic acid synthases polymerize hyaluronic acid using activated uridine diphosphate-sugar nucleotides as substrates." (emphasis added). (Response, page 10).

Thus, both Smeekens and applicant teach an enzyme which uses small sugars or sugar-like molecules to synthesize large polymers. Both Smeekens and applicant

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teach or suggest plants of both which make large polymers, hyaluronic acid and starch, fructan, or levan respectively. Both Smeekens and applicant teach or suggest large polymers not naturally found in plants and which are synthesized from building blocks of sugar like molecules: Levans or microbial fructans and hyaluronic acid respectively.

Applicant urges that "one of ordinary skill in the art would not have been motivated to combine Smeekens and DeAngelis" because DeAngelis discloses hyaluronan synthases that produce large polysaccharides which cannot provide the sweetening power sought by Smeekens.

This is not persuasive because the motivation to combine is not the provision of sweetening power sought by Smeekens, but is instead the scalable and plant based production of carbohydrates as taught by Akasaka.

One skilled in the art would have been motivated to generate the claimed invention because it is well known that reactor-based production using bacteria leads to the contamination by bacterial hemolytic toxins such as streptolysin as taught by Akasaka (column 1, lines 15-60) and that reactor-based production is not scalable and is more expensive than plant based production as taught or suggested by Mattes and by Smeekens. (Mattes, et al., @ column 1, line 20-26; Smeekens @ column 3, line 4). (Office Action, page 18).

Applicant urges that there is a lack of reasonable expectation of success because the fructosyltransferases disclosed by Smeekens and the hyaluronic acid synthases disclosed by DeAngelis are different. (Response, page 10).

This is not persuasive because the ordinarily skilled artisan would recognize that even though two enzymes with different functions produce different products, because the enzymes are in the same class, there is indeed a reasonable expectation of success.

Applicant urges that Smeekens does not teach non-naturally occurring polymers or high molecular weight or high degree of polymerization. (Response, page 10).

This is not persuasive because the argument proceeds from a false premise. Smeekens does indeed teach non-naturally occurring high molecular weight bacterial fructan polymers. (Smeekens, column 4, lines 1-50, particularly lines 7-10).

Applicant urges that the deficiency of Smeekens and DeAngelis is not cured by Akasaka or Mattes because none of them provides the required motivation to combine and reasonable expectation of success. (Applicant's Response, filed 4/24/07, pages 11).

This is not persuasive "because it is well known that reactor-based production using bacteria leads to the contamination by bacterial hemolytic toxins such as streptolysin as taught by Akasaka (column 1, lines 15-60) and that reactor-based production is not scalable and is more expensive than plant based production as taught or suggested by Mattes and by Smeekens. (Mattes, et al., @ column 1; line 20-26; Smeekens @ column 3, line 4)". (Office Action mailed 1/24/07). Moreover, the teaching in Smeekens that non-naturally occurring bacterial polymers can be made in plants does indeed provide reasonable expectation of success.

In response to applicant's argument that "... none of the references alone teach the composition as claimed," the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references

would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Remarks

10. All claims remain rejected. This rejection is made FINAL.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

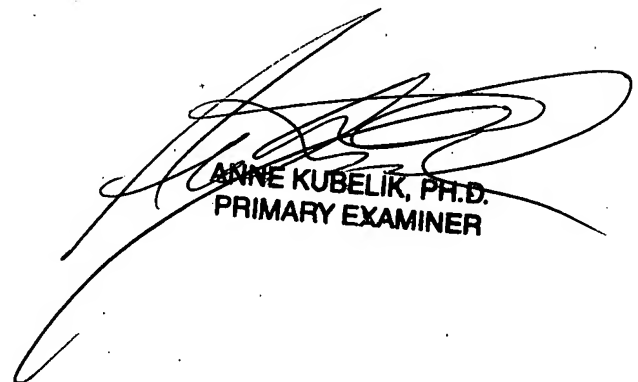
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bob



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER